
**FDAMA Stakeholder's Meeting
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**State-of-the-Art Science and Risk-Based
Decision Making**

- Create Technical Advisory Boards
 - Mixed Board (Academia, Industry, FDA)
 - Recommend to Agency when a National Forum needs to be held
 - Forum Focus
 - Open data presentation
 - Risk base analysis
 - Create climate where problems can be discussed



**Facilitate the Exchange and Integration of Scientific
Information for Agency Scientists**

- Hire and maintain **Experienced & Pragmatic staff**
- Provide opportunities for Agency scientists to engage in laboratory research
 - Sabbaticals
 - Corporate Internships
- Have scientists from industry present state of the art symposiums to FDA scientists
- Use Technical Advisory Board as a forum to discuss new information, advise FDA and hold appropriate symposium



Educating the Public - Risks Against Benefits

- Better educate the public on the basis for the approval of new medicines
- Provide the public with better information about the pharmaceuticals they have been prescribed
- Look at using a publicly supported forum like National Public Radio/Television for patient education - FDA Fireside Chats



Limited Resources - Achieve the Greatest Impact

- Partner more actively with product sponsors
- Use Advisory Committees to establish priorities for Fast Track products
- Influence sponsors to positively enable FDA review process
 - FDA sponsored workshop that would focus on what reviewers want to make their life easier
- Reassess the Inspection Programs
 - Decide what type of inspection is giving the most "Bang for the Buck"
 - A firm with good regulatory standing should be inspected less frequently than a firm with a poor inspection history



Stakeholder Communications

- Continue to seek stakeholder input
- Continue to develop draft guidance and keep Industry Informed
 - Involve industry in the creation of draft guidance
- Implement modernization effectively and consistently
 - Harmonize Guidance and Process across Centers
 - Harmonize Globally
 - Partner effectively with Pharmacopeias


